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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/676,005 | 10/02/2003 | Norman L. Anderson | | 6420 |

7590 10/07/2005

Hendricks and Associates
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Fairfax, VA 22031-2509

EXAMINER

HINES, JANA A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1645

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/676,005

Applicant(s)

ANDERSON, NORMAN L.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-26 and 37-41 are drawn to a method for quantifying the amount of at least one target protein in a sample, classified in class 436, subclass 176.
 - II. Claims 27-31 and 42-43 are drawn to a method for capturing similar amounts of 2 or more different monitor peptides from a sample containing widely varying concentrations of the different monitor peptides, a support system and a kit classified in class 436, subclass 174.
 - III. Claims 32-34 are drawn to a method of measuring the progress of proteolytic digestion of a sample, classified in class 436, subclass 177.
 - IV. Claim 35 is drawn to a method of quantifying the amount of at least one target protein in a sample further comprising two wash steps, two elution steps and a subjection step, classified in class 436, subclass 178.
 - V. Claim 36 is drawn to a method of characterizing the structure of a target protein in a sample, classified in class 436, subclass 173.
2. The inventions are distinct, each from the other because of the following reasons:
 - (i) Inventions I, II, III, IV, and V are related as distinct methods because they are different methods with different method steps; reagents; functions and each result in different final outcomes. First, the instant specification does not disclose that these methods would be used together, rather the specification beginning at page 12

describes these methods as separate and distinct embodiments. The methods are all unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. Group I is the only method drawn to quantifying the amount of at least one target protein in a sample; while only group II is drawn to a method for capturing similar amounts of 2 or more different monitor peptides from a sample containing widely varying concentrations of the different monitor peptides. Thus each method is distinct because of the different steps and functions. Furthermore, each invention performs its function using different method steps and reagents. For instance, only group IV comprises a method of quantifying the amount of at least one target protein in a sample comprising a digestion step, a preparation step, an addition step, a loading step, a wash step, an elution step, a loading step, a second wash step, a second elution step and a subjection step; therefore this method is unlike the other groups. Only, group V is drawn to a method of characterizing the structure of a target protein in a sample comprising a subjection step, two separate digestion steps, a preparation step, a loading step, a wash step, an elution, a subjection step and a comparison step. Thus, each method results in different final outcomes. This method is separate and distinct from any other method. Therefore, each method is divergent with respect to the amounts of reagents used and their associated steps. For these reasons the inventions I, II, III, IV and V are patentably distinct.

Furthermore, searching the inventions of groups I, II, III, IV and V, would impose a serious search burden. The inventions have a separate status in the art as shown by

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their different classifications. A method drawn to quantifying the amount of at least one target protein in a sample requires a different search, than the other methods. Thus, a search drawn to a method for capturing similar amounts of 2 or more different monitor peptides from a sample containing widely varying concentrations of the different monitor peptides, is not necessary for a determination of novelty and unobviousness of the method of group V which comprises a subjection step, two separate digestion steps, a preparation step, a loading step, a wash step, an elution, a subjection step and a comparison step. Furthermore, the method of group IV may be known even if the method of group I is novel. In addition, the technical literature search for the method of group I and the method of groups II-V are not coextensive, since, for instance, the method group I may be characterized in the technical literature prior to discovery of the method of group II.

3. The inventions of Groups I-V have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I-V together.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different

products and/or method steps, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
September 26, 2005

A handwritten signature in black ink, appearing to read 'Ja-Na Hines', is written over the typed name and date.